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Implementing Ebola Testing: Rollout at the Bureau of Public Health Laboratories

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The *Ebola virus* (*Zaire ebolavirus*) (Figure1) is a causative pathogen of Ebola Virus Disease (EVD), a hemorrhagic fever with a mortality rate of 25 - 90%.[1] In March, 2014, an outbreak of the *Zaire* strain occurred in Guinea and spread to Liberia and Sierra Leone. As of April 2015, there are 25,551 cases and 10,588 deaths associated with this this outbreak. The rapid spread of this outbreak, coupled with the high number of airline flights from affected areas to the United States (US), prompted the US Centers for Disease Control and Prevention (CDC) to deploy an assay for the detection of EVD cases .

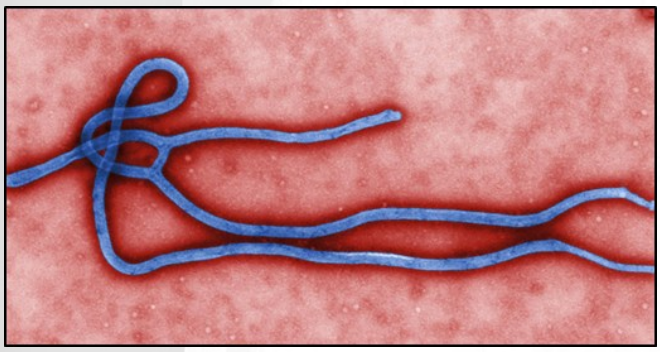

Figure 1. Ebola Virus. (Image source: Cynthia Goldsmith, CDC).

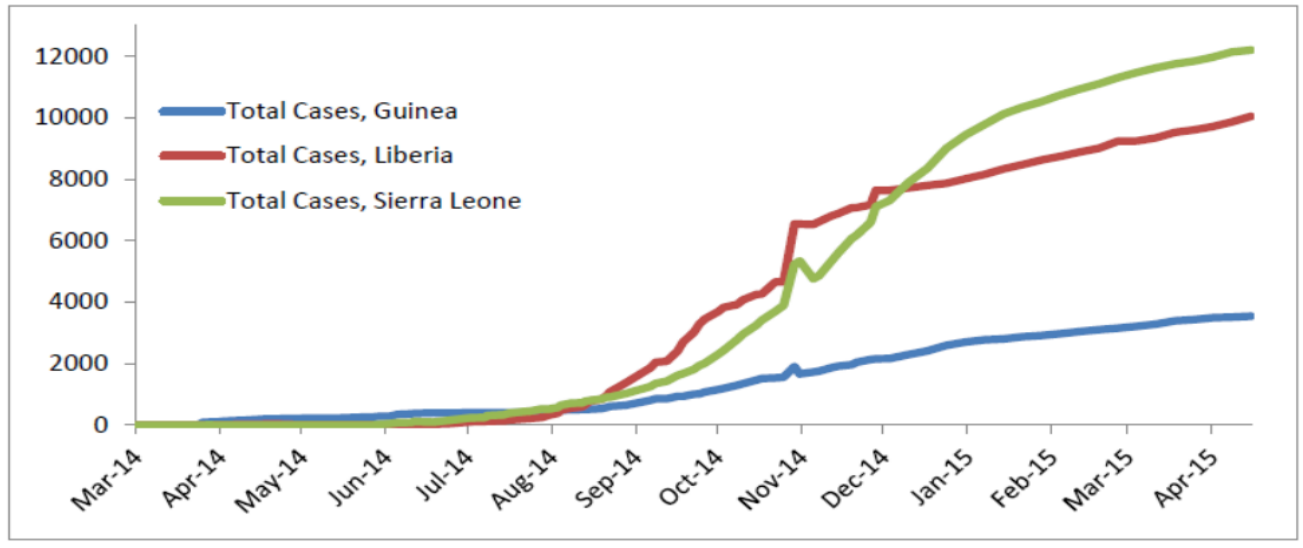

Figure 2. Total Ebola Cases in West Africa Outbreak Countries (Data source: World Health Organization Ebola Situation Report- 15 April 2015).[2]

In August 2014, the CDC requested 13 laboratories within the Laboratory Response to participate in the initial deployment of an assay developed by the Department of Defense. This assay, a real-time reverse transcription (rRT) polymerase chain reaction (PCR) test, utilizes a single gene target for detecting the Ebola virus *Zaire* strain in patient specimens. The Florida Bureau of Public Health Laboratories (BPHL)-Miami was among the initial reference laboratories chosen based on its proximity to an international airport and the presence of a thriving West African community from countries such as Ghana, Nigeria and Liberia, and Sierra Leone. The facility began accepting specimens within two weeks of the CDC's request.

The CDC issued an Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease (http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html)[4] to provide direction for laboratory workers submitting specimens for Ebola virus testing and confirmation.

BPHL subject matter experts developed and disseminated guidance documents for specimen collection, packaging, and shipping to the reference laboratories in Florida. (Ebola Virus Diagnostic Specimen Collection, Packaging, and Shipping Guidance for Laboratories and County Health Departments, and Point of Care Testing for Patients Suspected of Ebola Virus Disease or Confirmed Ebola Virus Disease is found at http://www.floridahealth.gov/diseases-and-conditions/ebola/#healthcare) [5].

One immediate concern for sentinel hospitals was the low supply of packaging and shipping materials available to submit suspect Category A specimens to the reference laboratory for testing. The Florida Department of Health coordinated the distribution of shipping supplies to 59 of the 67 county health departments (CHDs), to ensure adequate supplies would be available to each of the hospitals in the event of a suspect case. In addition, BPHL provided a refresher seminar on packaging and shipping training from November through April, to ensure proper packaging and shipping occurred for any suspected EVD cases.

The BPHL-Miami faced immediate challenges prior to implementing this assay, including the incorporation of resources on clinical presentation of Ebola Virus Disease for self-monitoring use into their standard operating procedures before suspect specimen processing could begin. The introduction of a new select agent and waste stream required the development of extremely defined tasks to use this new assay safely.

Another concern for the BPHL-Miami focused on the addition of Trizol to the blood in a 3:1 ratio to inactivate the virus. Trizol reacts with bleach to produce toxic fumes creating incompatibility issues with the typical waste streams containing bleach.[3] This necessitated the development of a novel waste stream that uses a quaternary ammonium disinfectant, such as Conflikt Detergent Disinfectant to replace bleach. In addition, the standard Personal Protective Equipment (PPE) utilized in the Biosafety Level 3 (BSL-3) laboratory, which consisted of a Tyvek suit, double gloves, and a full-face shield PAPR unit, had to be modified to include an impermeable barrier, a plastic apron, to protect the analyst.

Drawing on BPHL-Miami's experience, the BPHL laboratories in Jacksonville and Tampa have gained the capability for testing specimens suspected of containing Ebola virus by the end of 2014. The excellent work of the preparedness staff at the BPHL-Miami enabled the rapid development and deployment of emergency testing that will serve as a model for public health laboratories encountering emerging public health threats.

References.

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4. Interim Laboratory Guidelines for Handling/Testing Specimens from Cases or Suspected Cases of Hemorrhagic Fever Virus (HFV) Interim Laboratory Guidelines for Handling/Testing Specimens from Cases or Suspected Cases of Hemorrhagic Fever Virus (HFV) https://www.asm.org/images/PSAB/Ebola9-10-14.pdf
5. Ebola Virus Disease. Florida Health http://www.floridahealth.gov/diseases-and-conditions/ebola/#healthcare
6. "Trizol Reagent Material Safety Data Sheet" Life Technologies. MSDS ID: 15596026. October 2014.

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COLLEGE OF AMERICAN PATHOLOGISTS LABORATORY PREPAREDNESS EXERCISE CHALLENGE A

The 2015 College of American Pathologists (CAP) Laboratory Preparedness Exercise (LPX) challenge A mailed on Monday, April 6, 2015. Please note that several of the Sentinel Level Clinical Laboratory Guidelines For Suspected Biological Threat Agents And Emerging Infectious Diseases updated in 2014. For the latest revisions go to http://www.asm.org/index.php/issues/sentinel-laboratory-guidelines.

As part of the challenge, you are required to contact your Bioterrorism (BT) Coordinator at the Laboratory Response Network (LRN) reference laboratory if, after performing the established guidelines on an isolate, you are unable to rule out an agent of bioterrorism. Hopefully you did not wait until the end of the exercise to contact your BT Coordinator. The time interval between the date that guideline testing was initiated and completed (not the initial culture or subculture date) and the date that the next step took place for identification is monitored and should be reported in real time to your LRN reference laboratory.

In addition, Florida requires you to package and ship all suspected isolates to the attention of your BT Coordinator at your LRN reference laboratory. When all challenges are completed, the isolates can be mailed in the same package. If you have not already done so, please forward your isolates to the appropriate reference laboratory. Once received, the LRN reference laboratory will verify that proper packaging and shipping protocols were followed and they will document it. The LRN will not determine whether you correctly identified the challenge isolates, just whether you made contact with the correct laboratory in a timely manner and then packaged and shipped the isolate(s) correctly.

Remember, this is not a graded exercise so referring specimens to your LRN reference laboratory for purposes of this exercise will not violate the Clinical Laboratory Improvement Amendment (CLIA) Proficiency Testing rules. In addition, this exercise is exempt from the select agent regulations so there is no need to complete any of the select agent forms. All exercise materials and their derivatives must be destroyed upon completion of the exercise.

If you have any questions, please do not hesitate to contact Betty Wheeler at (904) 791-1568 (Betty.Wheeler@FLhealth.gov)

CHEMICAL THREAT (CT) PREPAREDNESS TRAINING

The CT laboratory coordinators continue to reach out to the health and medical community by offering training for CT preparedness at hospitals and county health departments (CHDs). This training covers chemical terrorism awareness and the collection of clinical specimens after a chemical terrorism event. Hospital and CHD staff play an important role in the response to a chemical exposure event since clinical specimens will be collected for analysis. For your convenience and to increase participation, this training can be presented at your facility. Each course lasts approximately one hour with one 15-minute break between courses. Florida clinical laboratory and nursing continuing education credits will be offered. Training manuals, "hands on" exercise materials, and CT preparedness kits will be provided. This training is recommended for physicians, nurses, epidemiologists, emergency department personnel, phlebotomists, hospital and health department laboratory personnel, and others who may collect clinical specimens. Contact the CT laboratory coordinators in your region for more information (see the Bureau of Public Health Laboratories Directory on the back of this document for contact information).

LABORATORY RESPONSE NETWORK (LRN) TRAINING—BIOLOGICAL DEFENSE

The BPHL is currently offering an LRN Sentinel Laboratory training course at no cost to you at your facility. This training follows the American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. Scheduling the training at your facility is a relatively easy process. Determine when you would like to have the training and how many people will be attending. A time will be set up that is convenient for all. The training materials are provided, as well as the biodefense reference manuals for your laboratory.

The training syllabus includes: 1) an overview of the LRN; 2) the ASM protocols for ruling out potential bioterrorism agents and how to refer a sample to the state LRN Public Health reference laboratory when a bioterrorism agent cannot be ruled out; 3) the role of the sentinel laboratory in responding to pandemic influenza; 4) a brief introduction to packaging and shipping of infectious substances; 5) an introduction to the CDC Select Agent Program; and 6) the College of American Pathologists Laboratory Preparedness Exercise (CAP LPX).

This class awards Florida clinical laboratory continuing education credits based on five hours of instruction. Please contact Betty Wheeler at (904) 791-1568 (Betty.Wheeler@FLhealth.gov) to schedule a class for your facility.

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